

Remarks

Claims 1-29 and 34-36 and 40-42 have been canceled without prejudice. Claims 38, 43, and 50 are canceled herein. Therefore, claims 31-33, 37, 39, 44-49, and 51 are pending. Applicants respectfully acknowledge the allowability of claims 31-33, 37, 39, and 44- 47.

Interview Summary

Applicants would like to thank the Examiner for his time and helpful comments regarding the rejection that were made in the telephone interview of April 12, 2007. During the interview, Applicants informed the Examiner of the intent to cancel claims 38, 43, and 50. The remainder of the interview focused on understanding the nature of the rejection of claim 48 and reaching an understanding of what each side's position was regarding this rejection. The Examiner stated that Applicants should focus on showing that the limitation "wherein the truncated toxin moiety bypasses the inhibitory effect of pre-existing anti-diphtheria toxin antibodies" is a generic disclosure rather than an undefined species as he has interpreted the limitation.

35 U.S.C. § 112, first paragraph

Claims 38, 43, and 48-51 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to provide written description to reasonably convey to one of skill in the art to make or use the invention.

Regarding the rejection of claims 38, 43, and 50, although Applicants disagree with the rejection, in an effort to further prosecution, Applicants have canceled claims 38, 43, and 50 herein. Applicants believe this rejection to be moot in light of the cancellation of the rejected claims and respectfully request that the rejection be withdrawn.

Regarding the rejection of claim 48 under 35 U.S.C. 112, first paragraph, the Examiner alleges that there is a lack of written description support for a "truncated toxin moiety not that bypasses the inhibitory effect of pre-existing anti-diphtheria toxin antibodies." In particular, the Examiner contends that the support Applicants provide is directed to "a single undefined construct" and thus "cannot support the generic immunotoxin of the instant claims." Applicants respectfully traverse this rejection. Although Applicants support for this limitation appears in the

context of Example 9, Applicants contend that the support does not describe a single species, but a genus. In particular, the description on page 40, lines 28-32 refers to the construction of a C-terminal deletion mutant. The Examiner explained in the interview of April 12, 2007 that the use of the phrase “a single-chain immunotoxin was constructed with a C-terminal deletion mutant of DT” indicated that only one such mutant was contemplated. However, Applicants respectfully point out that the term “a” used in this context refers to more than one species. In fact, Applicants allowed claim 45 describes 3 species that would fall within this genus, namely truncations of 145, 150 and 152 C-terminal amino acids. Moreover, within the context of having created a truncation mutant as described on page 40, Applicants provide on page 41 the use of MSPΔ5 (a truncation mutant missing 150 C-terminal amino acids) and sFV-DT390 (a truncation mutant missing 145 C-terminal amino acids), two truncation mutants. Furthermore, Applicants describe on page 9, lines 15-16 of the specification that “numerous DT mutant toxin moieties are described herein.” Applicants describe on page 39 lines 1-14 that experiments were conducted to avoid pre-existing anti-DT antibodies. In these experiments it was discovered that “a C-terminal truncation mutant could not absorb the inhibitory effect, suggesting that the last 150 amino acid contain the epitope(s) recognized by the inhibitory antibodies.” Thus, Applicants realized and described that many C-terminal truncation mutants would avoid the inhibitory effect of pre-existing anti-diphtheria toxin antibodies. Applicants assert that reading the specification as a whole can only lead to the conclusion that the description provides support for a genus of truncation mutants that avoid the inhibitory effect rather than a single undefined species as alleged by the Examiner. Applicants believe this rejection to be overcome and respectfully request its withdrawal.

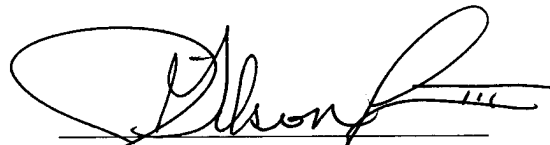
Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application are believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

ATTORNEY DOCKET NO. 14028.0290US
Application No. 09/389,565

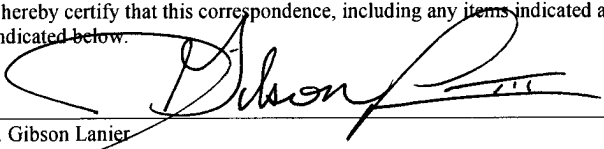
An EFS Web Filing Credit Card Payment Form authorizing payment in the amount of \$510.00, representing the fee for a Three Month Request for Extension of Time under 37 C.F.R. § 1.17(a)(3) for a small entity is being submitted electronically. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.


J. Gibson Lanier
Registration No. 57,519

NEEDLE & ROSENBERG, P.C.
Suite 1000
999 Peachtree Street
Atlanta, Georgia 30309-3915
678-420-9300 (Tel)
678-420-9301 (Fax)

<u>CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 C.F.R. § 1.8</u>	
I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted by EFS-WEB on the date indicated below.	
 J. Gibson Lanier	Date <u>5/15/07</u>